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Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2953567

January 17, 2002

Minoru Yokoshima, President
International Marine Products, Inc.
500 E. 7th Street
Los Angeles, CA 90014

WARNING LETTER

Dear Mr. Yokoshima:

On August 29, 2001, we inspected your seafood processing facility, located at 1741 South Mojave Road, Las Vegas, Nevada, and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your tuna, mackerel, and yellowtail to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

The deviations were as follows:

1. You must have a written HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for mackerel and yellowtail does not list the food safety hazard of histamine formation due to time/temperature abuse.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for tuna lists a critical limit, "Tuna must be 40°F or less," at the receiving critical control point, that is not adequate to control the food safety hazard of histamine formation. Because you purchase histamine forming fish from other processors, you are responsible for ensuring that the fish you receive are handled in a safe manner during transport. This can be accomplished by maintaining transportation records for all lots showing that the fish have been held at 40°F or less throughout transit or checking the adequacy of the cooling medium in a representative

number of boxes [the cooling medium must completely surround the product]. This requirement applies to all histamine forming fish, including mackerel and yellowtail.

3. You must have a HACCP plan which lists the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits, to comply with 21 CFR 123.6(c)(4). However, your procedure for monitoring refrigerated storage for tuna and for mackerel and yellowtail is inadequate in that the temperature is not monitored continuously. You may either monitor the adequacy of ice or cooling media twice a day or monitor the temperature of the storage chamber continuously by means of a temperature data recorder or by using an alarm system.

4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for tuna, mackerel and yellowtail at the receiving and refrigerated storage critical control points to control pathogens/histamines are not adequate if the temperature of the fish is found to be between 40° F and 45° F. Further cooling of the fish at refrigerated temperatures does not prevent adulterated product from entering commerce. You need to evaluate the total exposure time of the fish to elevated temperatures as well as address the cause of the process deviation. Please refer to the FDA Fish & Fisheries Products Hazards & Controls Guidance.

We observed similar HACCP deviations during the previous FDA inspection of your facility on June 9 and 10, 1998. We reported the deviations to you, by correspondence from this office, on August 5, 1998. Your firm responded on August 27, 1998. We found a few deficiencies in your response and responded back to you on November 2, 1998. Your subsequent response on November 16, 1998 and revised HACCP plans were satisfactory as we indicated in our letter of December 7, 1998.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Mr. Ken Murao, Branch Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the HACCP plans, temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond,

we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosure:
Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

cc: Ken Murao, Branch Manager
International Marine Products, Inc.
1741 South Mojave Road
Las Vegas, NV 89104